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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,873	09/25/2001	Rony A. Abovitz	4204.6-2	9194
7590	09/09/2004			
HUBBARD, MARC Munsch Hardt Kopf & Harr, P.C. 4000 Fountain Place 1445 Ross Avenue Dallas, TX 75202				EXAMINER KRONENTHAL, CRAIG W
				ART UNIT 2623
				PAPER NUMBER DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/963,873	ABOVITZ ET AL.
	Examiner Craig W Kronenthal	Art Unit 2623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) 2,3 and 8 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 March 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/9/02</u>	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

Claim Objections

1. Claim 2 is objected to because of the following informalities:

- Lines 9 and 10 are not grammatically correct. It is believed that “registration artifact frame second perspective” should be replaced with “registration artifact from a second perspective”.
- Line 17 seems to repeat what is said in lines 14-16. It is believed that “registering the fluoroscopic images” in line 17 should be deleted.

Appropriate correction is required.

2. Claims 3 and 8 are objected to because of the following informalities:

- In line 2 “a” should be replaced with “an”.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5-7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Haim et al. (WO 98/35720). (hereinafter Haim)

Regarding Claim 1: Haim discloses a registration artifact (20) for use in registering fluoroscopic images (60, 80) comprising:

- A plurality of radio-opaque fiducials (22a, 22b, 22c, 23) arranged in a known geometric relationship; and (p. 20 lines 10-12)
- A plurality of spatially trackable markers (22a, 22b, 22c, 23) disposed on the artifact in a known geometric relationship to fiducials. (p. 20 lines 10-12)

Haim's fiducial markers also serve as spatially trackable markers. Haim explains how these markers are used for tracking on p. 22, lines 16-26.

Regarding Claim 2: Haim discloses a method for registering fluoroscopic images comprising:

- Capturing a first fluoroscopic image (60 or 80) of a patient and a registration artifact from a first perspective, the registration artifact including, a plurality of radio-opaque fiducials arranged in a known geometric relationship and a plurality of trackable markers disposed in a known geometric relationship to fiducials; (see regarding claim 1 above)
- Determining the position of the registration artifact in the first fluoroscopic image with respect to a known coordinate frame by determining the position of the markers using the tracking system (p. 20 lines 24-26)

- Capturing a second fluoroscopic image of the patient and the registration artifact from a second perspective (see regarding claim 1 above) – It is anticipated that the capturing of a second image would be done in the same manner as capturing the first image. Haim explains that a second perspective could be the result of patient movement, or acquired from a different view angle or having a different scale from the previous image (p. 23 line 28 – p. 24 line 2).
- Determining the position of the registration artifact in the second fluoroscopic image with respect to the known coordinate frame by determining the position of the markers using the tracking system (p. 20 lines 24-26) - It is implied by Haim that the steps used in determining the artifacts position in the first image would be the same for a second image
- Registering the first and second fluoroscopic images using the positions of the fiducials in each fluoroscopic image and the determined position of the registration artifact (p. 24 line 2) – The coordinates are determined by the fiducial points as explained p. 20, lines 24-26. Haim even explains the registering of a CT image with a fluoroscopic image and the importance of the fiducial points to this process (p. 24 lines 23-25).

Regarding Claims 5 and 10: Haim discloses the registration artifact of claim 1, wherein the trackable marker includes a magnetically trackable object (24). As explained on p. 20 lines 8-9 and demonstrated in Figure 1B a marker (23) may comprise a magnetic

device (24). Haim also explains how the device (24) is used to magnetically track the position of the registration artifact and its markers (p. 20 lines 13-17).

Regarding Claim 6: Haim discloses the registration artifact of claim 1, further comprising a radio-transparent body to which the plurality of fiducials and plurality of spatially-trackable markers are mounted (p. 20 lines 4-6).

Regarding Claim 7: Haim discloses an image guided surgery system comprising:

- A registration artifact, including a plurality of radio-opaque fiducials arranged in a known geometric relationship, and a plurality of spatially trackable markers disposed on the artifact in a known geometric relationship to fiducials (p. 20 lines 4-6)
- A tracking system for determining the positions of the plurality of trackable markers (p. 21 lines 10-16)
- A computer in communication with the tracking system for receiving information on the positions of the trackable markers (p. 21 lines 16-19); the computer adapted for receiving a fluoroscopic image taken of the patient with the artifact in the picture (p. 21 lines 29-31) and registering (p. 23 lines 29-31) the image using the positions of the trackable markers when the fluoroscopic is taken, the positions of the radio-opaque fiducials within the fluoroscopic image and the known relationship between the plurality of trackable markers and the plurality of radio-opaque fiducials (p. 20 lines 24-26)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haim in view of Cosman (P.N. 6,405,072). Haim discloses the registration artifact of claim 1, including trackable markers. However, Cosman discloses the markers of the reflecting type, specifically one with an infrared light source (col. 4 lines 25-27). It is well known to those skilled in the art of illumination that light emitting diodes or LED's are often used light sources in applications requiring smaller dimensions. Furthermore, it would be obvious to modify Haim in view of Cosman because as Cosman states "the fiducial marks have individual shapes or other features, differing one from another, so that each of the marks may be easily individually identified" (p. 20 lines 22-24).

7. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haim in view of Leibinger et al. (P.N. 5,394,457). (hereinafter Leibinger) Haim discloses the registration artifact of claim 1, including trackable markers. However, Haim does not disclose the markers having a specific shape. Leibinger discloses a trackable marker that is both reflective and spherical. Leibinger's marker

"contains a substance which will give sharp contrast to the image in the image generation process" (col. 1 lines 50-52). Leibinger later teaches that metal such as titanium is a suitable material for the marker (18) (col. 6 lines 7-9). One skilled in the art would know that metals such as titanium are reflective substances. Furthermore, Leibinger explains why a spherical shape is preferred for fiducial markers (col. 6 lines 20-31). One skilled in the art would be motivated to modify Haim in view of the teachings of Leibinger to improve tracking accuracy by making the fiducial markers more easily identifiable within fluoroscopic images.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Acker (P.N. 5,729,129) is cited for teaching the ability to track fiducial markers using magnetic properties.
- Allen (P.N. 5,397,329) is cited for teaching a fiducial marker system.
- Heilbrun et al. (P.N. 6,165,181) is cited for teaching a fiducial structure containing a plurality of fiducials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Craig W Kronenthal whose telephone number is (703) 305-8696. The examiner can normally be reached on 8:00 am - 5:00 pm / Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 306-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CWK
8/18/04



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